

## REMARKS/ARGUMENTS

### THE INVENTION

This invention provides for a novel method of treating postpartum psychosis using a glucocorticoid receptor antagonist (GRA). Before this invention, there was no report that postpartum psychosis was due to a glucocorticoid regulatory dysfunction and treatable with GRAs.

### STATUS OF THE CLAIMS

Claims 1-14 were pending. Kit claims 12-14 are canceled. New claim 15 is added. Claim 15 finds support in original claim 12 reciting a specific GRA and at paragraph [0028] which provides a definition.

### REJECTIONS

#### 35 U.S.C. §102.

The pending claims are rejected as anticipated over the applicant's earlier patent, U.S. Pat. No. 6,150, 349 ['349]. The Examiner has directed applicant's attention to that portion of the '349 patent that describes postpartum psychosis as a psychotic disorder classified by the DSM IV as "not otherwise specified" (see column 15, lines 46-55). The Examiner interprets this paragraph as suggesting that postpartum psychosis is treatable by GRAs.

When applicant filed the '349 patent, they described their invention as the "treating of psychosis **associated with glucocorticoid related dysfunction** by administration" of a GRA (column 3, lines 46-49). The claims of the '349 patent are limited to treating psychotic major depression. At columns 5-7 of the '349 patent, there is an extensive discussion defining psychosis. There, the patentees explain that psychosis is a symptom of many different diseases and that psychosis has different causes—some are treatable by GRAs, and others are not

treatable. Postpartum psychosis is not listed as one of the treatable psychoses. When the '349 patent was filed, the psychotic features of schizoaffective disorder was thought to be treatable by GRA therapy. In a clinical trial conducted by the applicant, it was determined that GRAs had no effect on the psychotic features of schizoaffective disorder. (See Exhibit 1, Declaration dated January 20, 2000, at Section 7, page 15, entitled: "Schizoaffective disorder tests did not work.")

Having explained that not all psychoses arise from glucocorticoid regulatory problems, applicant emphasizes that the subject invention is the discovery that postpartum psychosis is caused by a glucocorticoid regulatory dysfunction and is thus treatable by GRA therapies. According to the DSM IV, postpartum psychosis is classified separately from other psychiatric disorders having psychotic features. It is considered by the DSM and by the medical community to be a distinct psychiatric disorder of unknown etiology. No prior art reference has been cited to make the connection between postpartum psychosis and glucocorticoid regulatory dysfunction.

So why does the '349 patent recite postpartum psychosis on column 15 of the '349 patent? Although, the Examiner has interpreted this text to support a position that all the listed forms of psychosis are treatable by GRA, the text of the '349 patent does not make that connection. Column 15 merely provides a general description of how to diagnose the various forms of psychosis.

Had the '349 patent stated that these miscellaneous disorders associated with psychosis were treatable by GRA therapy, the '349 patent would be a §102 bar. But the '349 patent makes no such statement. Columns 12-15 of the '349 patent are entitled, "Diagnosing and assessing conditions and illnesses involving psychosis." It is a comprehensive description derived from the DSM IV. And at column 15, the last paragraph of this section explains that the DSM IV has a miscellaneous section of disorders with psychotic features where the causes are unknown. That section included postpartum psychosis.

A mother who has recently completed her pregnancy undergoes a complex and not well understood process of adjusting from carrying a fetus to nurturing a baby. The

hormonal changes occurring in the first few weeks are enormous. When psychosis occasionally appears in these mothers, it was simply an unexplained medical event.

The Examiner is respectfully asked first to revisit the language of the '349 patent and to take note of the fact that the '349 patent and the subject application name the same co-inventor, Dr. Joseph Belanoff. The section describing postpartum psychosis is simply a part of the section generically teaching how to diagnose psychosis. There was no suggestion in the patentee's specification that all of the psychotic associated disorders listed in the DSM IV were in fact due to a glucocorticoid regulatory dysfunction and in fact treatable by GRAs.

Having explained:

- that the '349 patent describes a laundry list of all known types of psychosis in a section defining *how to diagnosis* psychosis;
- that the '349 patent expressly limits its therapies to those psychoses associated with glucocorticoid regulatory dysfunction; and,
- that the '349 patent claims are limited to treating psychotic major depression;

it is urged that the '349 patent does not state or suggest that postpartum psychosis is among those psychoses that are amenable to GRA therapy. It merely lists postpartum psychosis as a disease involving psychosis along with every other known psychiatric disorder involving psychosis. Generally teaching the reader how to diagnose and assess the various types of psychoses is not a declaration that all psychoses are related to glucocorticoid regulator dysfunction and treatable with GRAs. Without such a declaration, the '349 patent cannot be a §102(b) bar to the subject claims.

### 35 U.S.C. §103

Claim 7 depending from claim 1 and reciting a specific GRA is rejected as obvious over the teaching of the '349 patent and Bradley (2002) reciting the GRA of claim 7.

Applicant relies on the remarks set forth above for claims 1-11 in view of the '349 patent. The '349 patent does not state or suggest that postpartum psychosis is one of the

psychotic features arising from glucocorticoid dysfunction. The addition of Bradley does not correct this fact.

#### DOUBLE PATENTING

The subject application is rejected under the doctrine of double patenting in view of the '349 patent. This is an academic rejection. The '349 patent issued in 2000. For purposes of novelty under 35 U.S.C. §102, the '349 patent is a §102(b) reference because the subject application has a 2003 priority claim. If the Examiner maintains his rejection under §102, a terminal disclaimer cannot avoid the impact of the '349 patent.

#### CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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